

REMARKS

The amendments to this patent application are as follows. The title and specification are being amended to emphasize "cerebral paralysis". The subject matter of previously deleted pages 8, 9 and 10 is being reinserted into the specification. Page 4 of the specification is being amended to include additional descriptions of the elastic tie rods. Claims 11, 12 and 13 are being canceled without prejudice. New claim 14 is being added. Claim 11 is being canceled to overcome the formal rejection. Withdrawal of the ground of rejection under 35 U.S.C. 112 is respectfully requested.

The Applicant does not seek a patent for a method, due to the fact that the method may be varied depending on an individual approach to every particular patient in every specific case.

It is the claimed device that has been able to render help to as many as thousands of sufferers from such a grave illness as cerebral paralysis. This fact is confirmed by the professional recognition by specialists in the art in many countries around the world. Please refer to the enclosed Declarations for Exhibits A, B, C, and D.

The Applicant would like to emphasize the fact that throughout the period of pendency of this patent application, that the single object being pursued is to set forth the principal characteristic feature of the invention. This feature is a possibility of

treating diseases which are exclusively cerebral in origin; and this is the gist of the invention's practical use and which gives high-efficiency and positive results.

The Applicant maintains the original position for patentability based upon specified objectives, advantages, and field of application of the invention. The Applicant believes that the subject-matter of the invention is novel and unobvious, as being applied for the first time in the world for treating patients with cerebral-origin diseases.

§ 112

Notwithstanding, there may be slight likeness or identity which may occur between the construction of the means for adjusting the tension of elastic tie-rods and of the lock, and that used in other prior art, e.g., as partly disclosed in *U.S. Patent No. 5,308,305* issued to J. Romney on May 3, 1994, or in *U.S. Patent No. 807,908* issued to H. Bradstreet on December 19, 1905. That is why claim 14 recites elements as a means or step aimed at performing a definite function, without disclosing a specific construction ensuring that function (U.S.C. 35 #112, paragraphs 2, 3).

The foregoing refers immediately to claim 14, because claims 11, 12 and 13 have been deleted. The aforesaid limitations are based on the specification of the invention which reads as follows: "the tension adjuster may be of any other construction performing a similar function, i.e., a possibility of tensioning the elastic tie-rods" (see lines 8-9 of page 6 of the specification); "the lock

of the tension adjuster may feature any construction capable of performing the function of retaining the position and the tensioning force of the elastic tie-rods (see lines 20-22 of page 6 of the specification).

In addition, in order to avoid prior art teachings, it is necessary to restrict the field of application of the invention by amending the title thereof as follows: "Device for treatment of patients with disturbed posture and motor activity resulting from cerebral paralysis".

Also, a revision is included in the preamble of new claim 14, that is, "resulting from cerebral paralysis". Two further features are being recited in claim 14, i.e., a means for adjusting and selecting the force of action of the elastic tie-rods, and "a means for retaining the assumed position of the elastic tie-rods and the tensioning force thereof".

As regards the unpatentability of claim 14 over *Bradstreet U.S. Patent No. 807,908*, this rejection is respectfully traversed.

The device disclosed in *Bradstreet* comprises only two supporting elements located on the feet (D) and the waist and appearing as a belt 1, and a pelvic support (3), since the term "support" implies necessarily the presence of a zone of application of the forces exerted by elastic elements.

The oblique and ring-shaped grids located around the ankles, under the knees, on the shoulder girdle, in the region of the elbow, and at the wrist taught in *Bradstreet* (ref. nos. 7, 13, 12, 22, respectively) are not in fact the supporting elements. This is because they cannot perform the function of such elements as being readily displaceable under the action of the forces exerted by the main longitudinal elastic straps and serve as displacement restrictors of these longitudinal straps. The device comprises two main elastic straps which establish a single system of tie-rods and run lengthwise along the trunk and thighs from the anchoring points on the belt at front, then are thrown over the shoulders, run down to the anchoring points on the belt at the rear and further from these points to the lower limbs, thus prolonging the system downwards. The front and rear straps are bifurcated at the thigh and go to the lateral surfaces of the shin and to the feet to be held there in position. Provision is also made for a plurality of transverse and obliquely running small straps on the trunk and arms.

Thus, the elastic straps taught in *Bradstreet* (that is, the respective front and rear straps 4,5; the obliquely running straps 8; the thoracic straps 11; the arm straps 14; the main straps 20,21 running along the thigh; the thigh strap 27; and the shin strap 23) are not arranged in antagonistic pairs nor are they connected to two supports as contended by the Examiner. The aforesaid support 3 appearing as a belt and serving as the pelvic support, performs but a limited function consisting mainly in pressing the vertical

straps against the trunk.

It is respectfully submitted that the prior art device is constructed as a single system not interconnected by any supports and is essentially an enclosed space featuring the force application points at the shoulders and feet. Moreover, the prior art system does not comprise a means (A) for adjusting the straps for tension. FIG. 6 presents a means (system) for interconnecting the vertical elastic straps with the aid of which straps can be positioned at any place wherever it becomes necessary, e.g., at the wrists, ankles, etc.

In view of the fact that the prior art device is devoid of independently functioning elastic tie-rods exerting action upon the individual groups of muscles, this prior art device cited against the claimed invention cannot be used for correcting the mutual position of the parts of patient's body. Hence, the prior art device will not find application for treating cerebral-original neurological disorders.

Because the Patent Examiner is suggesting that the technical improvements attainable by the present invention be demonstrated more clearly and indefiniteness present in the claims be eliminated, a more complete and definite description of the construction recited in the present invention is described as supports and elastic tie-rods with tension adjusters.

As recited in lines 27-34 of page 5 and in lines 1-7 of page 6 of the specification, the claimed device comprises supports placed on patient's trunk as follows: a pelvic support appearing as a belt, and shoulder supports; supports placed on patient's limbs as follows: elbow, hand, finger, knee and pedal supports. All the supports mentioned above are interlinked through fixing elements appearing as elastic tie-rods which may interconnect both adjacent and nonadjacent supports.

The elastic tie-rods are arranged on the surface of the patient's body in substantially antagonistic pairs so as to follow the anatomical arrangement of the skeletal muscles. This means that each elastic tie-member has its antipode or opponent. That is, some of the elastic tie-rods are located on patient's body to the right of the spine, while the other tie-rods are situated to the left of the spine, or some of them are arranged at the front of the trunk and limbs, while the other ones, at the rear thereof. That is, the words "antipode" and "antagonist" are synonyms.

Thus, it is the disposition of the elastic tie-rods in antagonistic pairs so as to follow the anatomical arrangement of the device which is adapted to accomplish the object of the invention, if and only if the elastic tie-rods are situated in a strict symmetry with respect to the spine and in accordance to the anatomical structure of human body.

According to the claimed device, a clearly defined dynamic supporting structure is provided, appearing as a functional corset (lines 31-33 of page 6 of specification), the use of which gives a possibility of restoring a new position of patient's body and limbs closely resembling the physiological one.

The claimed device is provided for and aimed at treating patients with disturbed posture and motor activity due to cerebral paralysis which exhibits such disturbances as triple flexion of the lower limbs complicated with contractures in the ankle joints, uncompensated forward incline of patient's body, difficult motion, pathological gait, and so on. This is why any patient needing treatment with the aid of the claimed invention can receive such treatment. This is because the claimed device allows for the replacing of static (passive) correction of the pathological positions of the trunk and limbs with a functional (active) correction. The invention also allows for the rearranging of the previous pathologic stereotype of the posture and motions in the central and peripheral nervous systems.

The claimed device is instrumental in fixing patient's joints in a required position from the instance when a force arises contributing to flexion, extension, rotation, adduction, and abduction of the limbs and trunk as follows. The claimed device is put onto a patient with relaxed muscles and those elastic tie-rods are tensioned which correct the position of the patient's body parts to be treated (e.g., deformed trunk and lower limbs).

The elastic tie-rods are tensioned with the aid of tension adjusters until the normal physiological position is attained. That is until elimination of a pathological arrangement of the trunk and limbs is achieved but retaining a possibility of performing motion with an amplitude approximating the maximum one in a given particular patient.

Thus, the claimed device fixes the parts of the patient's body in a required position relative to one another whenever the patient's muscles are relaxed, whereby the myogenic tonus of a muscle or of a group of muscles is balanced by an elastic tie-member. This is done by increasing its tension until a load appears in a respective group of muscles which in turn makes it possible, in case of necessity, to perform some motions, since elastic retainers place no limitation on motion when parts of the patient's body perform spatial movements but only require additional efforts on the part of muscles. Every kind of patient's motions is ensured by elastic tie-rods arranged on the surface of patient's body in antagonistic pairs. This is to follow the anatomical arrangement of the skeletal muscles with respect to joints, which is the principal subject-matter of the claimed invention.

The principal distinguishing feature of the claimed elastic tie-rods resides in their being shaped as bundles 18 to 26 in number and being used in a plurality of variants and with variable anchoring points with respect to both the bottom and top ends of

tie-rods.

Elastic tie-rods are largely interposed between the neighboring support elements separately for the trunk and limbs, in such a manner: shoulder supports and pelvic support in the form of a belt, on the trunk; hand support in the form of a glove, elbow support, shoulder support, on the arms; pelvic support, knee support, shoe; and knee supports, shoe, on the legs.

The claimed device also comprises obliquely running elastic tie-rods, each having its own tension adjuster. Additionally, the fact that the claimed device is devoid of a connection between leg and arm or between both arms and hence of an influence of one arm on the other or on a leg, allows for independent correction of the foot, shin, and thigh for position.

As regards the supports claimed in the invention, all and each of them are the zones of application of forces exerted by the elastic tie-rods. That is, all the supports feature one elastic tie-rod terminating therein and another one starting therefrom. They are arranged in antagonistic pairs (the concept of antagonism being applied to the joints) with due account of the anatomical arrangement of the skeletal muscles.

Thus, for instance, the shoulder supports are fashioned as wide straps, wherein their lower portion comprise anchoring elements of the elastic tie-rods. These supports are located from

the neck to the shoulder joint and are intended for developing an adequately high friction between the strap and the patient's body with due account for keeping the strap against slipping in case of an asymmetric loading with the elastic tie-rods at the front and rear. This is due to the shoulder supports having different tension forces being applied at the breast and back, thus causing the trunk to flex or extend.

The elbow supports of the present invention are shaped as circular cuffs encompassing the region of the elbow joint. Provision of elbow supports is aimed at connecting the elastic tie-rods that run on one side from the shoulder and on the other side from the hand. This makes it possible to have functional loading of separate forearm and shoulder muscles during a treatment process.

The device claimed in the present invention comprises knee supports, each fashioned as a textile plate which encompasses the anterior and lateral knee surfaces and has fastening straps on the rear surface. There are also fastening elements in the form of a plurality of elastic tie-rods running from above along the thigh and from below along the shin.

The knee supports are used in the claimed invention for connecting the elastic tie-rods; in addition, they subdivide the tie-rods into two tiers, for the shin and for the thigh.

It is due to connection of the elastic tie-rods to the knee supports that correction of the foot, shin, and thigh for position can be performed in the claimed device independently, which extends the possibility of using diverse therapeutic techniques and modalities.

The pelvic support appearing as a wide exertion belt is also the zone of application of the forces developed by the elastic tie-rods. In the claimed device the trunk elastic tie-rods that run from above, terminate in the pelvic support, while starting at the latter support are the leg elastic tie-rods running downwards therefrom. The pelvic support develops loads on the upper and lower trunk portion.

In addition, it is important to present information on which skeletal muscles are the prototype for elastic tie-rods and which are not, because each of the elastic tie-rods has its antagonistic which is also a fundamental feature of the construction of the claimed device.

1. The following muscles are the prototype for the front elastic tie rods: the anterior scalene muscle (m. scalenus anterior); the middle scalene muscle (m. scalenus medius); the posterior scalene muscle (m. scalenus posterior); the long muscle of neck (m. longus colli); the internal oblique abdominal muscle (m. obliquus internus abdominis); the external oblique abdominal muscle (m. oblique internus abdominis); the straight abdominal

muscle (m. rectus abdominis); the iliopsoas muscle (m. iliopsoas).

The elastic tie-rods simulating the muscles located on the posterior trunk surface are not the prototypes for the muscles mentioned above.

2. The following muscles are the prototype for the rear dorsal elastic tie-rods: the shawl muscle (m. trapezius); the splenius muscle (m. splenius); the serratus muscle, posterior superior (m. serratus posterior superior); the serratus muscle, posterior inferior (m. serratus posterior inferior); the erector muscle of spine (m. erector spinae); the levator muscle of scapula (m. levator scapulae); the quadratus muscle of the loin (m. quadratus lumborum); the transversospinal muscle (m. transversospinalis); the semispinal muscle (m. semispinalis).

The elastic tie rods simulating the muscles located on the anterior trunk surface are not the prototypes for the muscles mentioned above.

3. The following muscles are the prototypes for the front elastic tie-rods located on the thigh: the iliopsoas muscle (m. iliopsoas); the tensor muscles of fascia lata (m. tensor fasciae latae); the sartorius muscle (m. sartorius); the straight femoral muscle (m. rectus femoris); the pectineal muscle (m. pectineus).

The elastic tie-rods simulating the muscles located on the posterior thigh surface are not the prototypes for the muscles mentioned above.

4. The following muscles are the prototypes for the elastic tie-rods located on the posterior surface of the legs: the greatest gluteal muscle (m. gluteus maximus); the gracilis muscle (m. gracilis); the biceps muscle of thigh (m. biceps femoris); the piriform muscle (m. piriformis); the gemelli muscles (m. gemelli); the great adductor muscle of femur (m. adductor magnus); the iliopsoas muscle (m. iliopsoas); the tensor muscle of fascia lata (m. tensor fasciae latae); the sartorius muscle (m. sartorius); the straight femoral muscle (m. rectus femoris); the pectineal muscle (m. pectineus).

The elastic tie-rods simulating the muscles located on the anterior surface of the legs are not the prototypes for the muscles mentioned above.

5. The following muscles are the prototypes for the external oblique elastic tie-rods located on the thigh: the iliopsoas muscle (m. iliopsoas); the greatest gluteal muscle (m. gluteus maximus); the middle gluteal muscle (m. gluteus medius); the least gluteal muscle (m. gluteus minimus); the quadriceps muscle of thigh (m. quadratus femoris); the sartorius muscle (m. sartorius).

The oblique elastic tie-rods located on the internal thigh surface are not the prototypes for the muscles mentioned above.

6. The following muscles are the prototypes for the internal oblique elastic tie-rods located on the thigh: the middle gluteal muscle (m. gluteus medius); the least gluteal muscle (m. gluteus minimus); the tensor muscle of fascia lata (m. tensor fasciae latae); the semitendinous muscle (m. semitendinosus); the semimembranous muscle (m. semimembranosus); the gracilis muscle (m. gracilis); the sartorius muscle (m. sartorius).

The oblique elastic tie-rods simulating the muscles located on the anterior femoral surface are not the prototypes for the muscles mentioned above.

Apart from the aforelisted construction features (i.e., elastic tie-rods and supports) the device also comprises a plurality of means for adjusting the tension of the elastic tie-rods. This means enable one to change and individually select the force of action on the patient's musculoskeletal system so as to suite the form of the disease and the degree of affection of the locomotorium (see lines 24-34 of page 4 of specification).

In addition, it is believed to be desirable to describe the prior art that is specified in the Certificate of International Search for International Application PCT/RU92/00247 and is set forth in subsequent publications, taking account of the fact that

many patent examiners in a number of countries made requests for such information.

1. One prior art device, that is, an orthopedic apparatus enabling paralyzed patients to stand (*Fr. A1, 2,298,314 published August 20, 1976*) is known to appear as overalls into which are built numerous components appearing as bands made of nonstretchable textiles, each fitting closely the pelvis, thigh, and shin, as well as comprises inflatable elements located along the legs, and rigid pins insertable in special wells or pockets.

A disadvantage inherent in this prior art device resides in the fact that it is intended only for imparting stability to paralyzed patients in the erect position in case of loose joints, whereby the field of application of this prior art device is restricted.

Another disadvantage of this prior art device may be regarded as its being devoid completely of structural elements for the upper trunk portion and for the arms, which makes it impossible to act on the muscular system of the shoulder girdle and may lead to its cardinal dysfunction.

It is worth noting that due to the aforesaid disadvantages this prior art device cannot be used under dynamic conditions, eg., while walking.

2. Another prior art device, that is, an orthopedic apparatus enabling paralyzed patients to stand (*Fr. A1, 2,390,152 published December 12, 1978*) is known to appear as overalls into which are built numerous components appearing as bands made of nonstretchable textiles and provided with velcro fasteners, inflatable chamber. These chambers, when inflated, impart regality of the overalls, rigid pins insertable in special wells or pockets and extending into the region of the knee and hip joints.

A disadvantage inherent in this prior art device, as well as in the preceding one, resides in that it fails to effect exercising the muscular system of the girdle, which may result in its cardinal dysfunction. This is because this device is intended only for imparting stability to paralyzed patients in the erect position in case of loose knee and hip joints, whereby the device is inapplicable under dynamic conditions, e.g., while walking which restricts the field of application thereof.

3. An additional prior art device (apparatus) providing an erect position of a patient and enabling him to walk (*EP A1 0066028, published December 8, 1982*) is known to appear as overalls. It comprises a corset, knee straps, shoes, and elastic metal plates interposed therebetween and arranged on the exterior lateral surfaces of thighs and on the interior lateral surfaces of shins.

The aforementioned prior art device is disadvantageous in being shaped as a large corset covering the majority of the body surface, whereby difficulties in body exchange may be encountered in patients due to poor heat transfer to the surrounding atmosphere from the body area involved.

Another disadvantage inherent in this prior art construction consists in the fact that the metal plates provided in the device function as flat springs only in one direction. That is, making the legs extend in the hip and knee joints, whereby the device proves to be a single purpose one to render help to patients who cannot move unassistedly. Thus, the field of application of the prior art device is very restricted.

4. A further device to facilitate walking (*SU, A1, 1,556,675, published April 15, 1990*) is known to comprise a fixing appliance having guides located at the front and rear thereof, and sleeves fitted movably and fixably in these guides.

The device is disadvantageous in its construction arrangement which provides for holding the lower portion of the trunk and legs, whereby the device can be used only for moving gravely ill patients.

Moreover, the entire system is made of rigid materials and is used in combination with a framework, which renders the device bulky and prevents a possibility of enhancing patient's activity in

walking, whereby therapeutical use of the prior art device is highly conjectural.

5. *USSR Patent Application SU A1 1,528,483 of December 13, 1989 issued to O.A.Ostapenko for "Device for relieving spinal column of load".*

This prior art reference is the closest reference to the claimed invention. It comprises a thoracic, a pelvic, and a pedal support, as well as fixing elements interconnecting these supports. The fixing elements appear as telescopic stands linking the pedal supports and the pelvic support to a bar having one of its ends coupled rigidly to the pelvic supports. The bar carries a reciprocatedly mounted roller fixed in position to the thoracic support. Two arms are held in place to the pelvic supports, the vacant ends of the arms being connected to springs mounted movably on the telescopic stands.

With the body of a patient assuming a vertical position the roller produces a slight reclining effect on the entire spinal column, while the thoracic support holds up the upper trunk portion. With the trunk inclined the roller rolls over the bar surface so as to assume an optimum position depending on the angle of trunk incline, and the springs transmit the force to the bar. Thus, the weight of the inclined trunk portion is compensated for and the muscular apparatus and spinal column are relieved from load.

A disadvantage inherent in this prior art device resides in its selective action, since this known construction is intended for facilitating active trunk forward inclines with subsequent treatment of a limited portion of the spinal column solely due to providing relief from the load. In addition, the use of this device may lead, due to its rigid fixing, to a restricted patient's mobility, followed by muscular atrophy and reduced activity of antigravity muscles. The treatment process using this known device is a prolonged one and hence impracticable for treating patients with disturbed posture and motor activity due to cerebral paralysis.

Thus, it is firmly believed that all cited references contain neither a combination of essential features of the claimed technical solution nor the principal objects of the invention. Furthermore, there are no technical solutions in the known references that are characterized by performing the functions identical to those of the claimed invention, as well as ways to attain the desired result, and the result itself.

In the course of treatment with the claimed device a new motion control stereotype is formed. In addition, patient's physiological position becomes dominating, with the resultant scope of motor activity, whereby the patient's posture can be corrected in cases where the disease is unamenable to treatment by other correction types (see lines 11-16 of page 7 of specification).

The principal object of the present invention is to apply the device, according to the invention, for nonoperative (conservative) treatment of the diseases of locomotorium resultant from various cerebral-origin neuropathies. These diseases lead to patient's pathologically disturbed position of the trunk and limbs, as well as motor activity.

Enclosed are four Rule 132 Declarations for Exhibits A, B, C, and D. These four Exhibits provide practical application of the invention which enable the attaining of further progress in technical results through patient's movements in a new position of his limbs and trunk. This leads to activation of the central brain structures due to reorganization of the system of control over the movements of both the locomotorium and the speech formation motor apparatus. This enables one to treat patients afflicted by the various forms of cerebral paralysis, as well as those suffering from post-cerebrovascular accident disturbance of motor activity.

Thus, these four Declarations for Exhibits A, B, C, and D provide new and unexpected results in the treatment of patients afflicted by cerebral paralysis which are exceedingly cogent evidence for the nonobviousness of the claimed invention.

In conclusion, the Applicants believe that the device for treatment of patients with disturbed posture and motor activity resulting from cerebral paralysis, is patentably distinct under 35 U.S.C. 103 over all the prior art references applied by the

Patent Examiner. Claims 11, 12 and 13 have been canceled. New claim 14 has been added. Applicants believe that this application, as amended, is now in condition for allowance. Early allowance of the claims and the application based upon the merits of this claim is respectfully requested.

Respectfully submitted,

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Enclosures: Declarations for Exhibits A, B, C and D

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Date: April 1, 1998



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